MDCG-NBO (Notified Bodies Oversight) Working Group

MINUTES

Date & time:	**15 June 2022** (10:00 – 17:30)
Venue:	**Hybrid meeting (Conference Center Albert Borschette, room AB-1B, 36 rue Froissart, 1040 Brussels, and Videoconference WebEx)**

1. Opening, minutes from last meeting and adoption of the agenda

COM welcomed participants to the second NBO meeting of 2022.

Participants were reminded that the draft minutes of the last NBO meeting has been sent out for feedback by 27 June 2022. No preliminary comments were shared.

The agenda was adopted with no changes in content.

2. Capacity of notified bodies

Following the mandate coming from EPSCO meeting on 14 June, MDCG is working on a preliminary list of actions to enhance notified body capacities and preparedness of economic operators to ensure the availability of safe medical devices. As agreed at the MDCG meeting on 20 June, the list is currently discussed by the Coordination Group of MDCG.

Several actions that would need involvement of designating authorities (DA)/NBO were presented and discussed. There was a general agreement on the need to take actions increasing the overall notified body capacity. However, DA appeared to be particularly concerned about the risk to modify the approach taken so far with reference to the need not to reduce, avoid or remove MDR/IVDR requirements.

Main points discussed were the following:

- Adoption of a Commission **Delegated Act to modify the frequency of full re-assessments of notified bodies**, based on Art. 44(11) MDR/Art. 40(11) IVDR. Some members asked for possible flexibility on the process, allowing for adapting the frequency on possible need that could arise (e.g. early re-assessment required based on outcome of DA's monitoring activities). Whilst the proposal was supported by all

NBO members, a few of them considered it only as a transitional measure to tackle the current challenges.
In addition to that, several NBO members asked for pragmatic solutions to facilitate applications for scope extension / lifting limitations without requiring a full Joint Assessment (JA) process. COM clarified that lifting limitations of designations should not be considered as extension of the scope of designation and thus do not trigger a Joint Assessment.

- Facilitating the use of **hybrid audits** in accordance with MDR/IVDR was also broadly supported by NBO, highlighting that the Regulations do not prevent notified bodies to already perform such hybrid audits, being different from remote audits. It was agreed to work on a common position including a definition of hybrid audits possibly addressing key elements.-. COM informed that it will take the lead of the relevant TF to start the work over the summer.
- Treatment of **SMEs**: It was agreed to further address the application of requirements laid down in MDR/IVDR Annex VII, Section 1.2.8. Reflections on the matter will start at the level of NBO TF on standard fees.
- Surveillance activities under the Directives: Several DAs expressed concerns on the proposal to adapt the requirements for the "**appropriate surveillance**" to be performed by notified bodies in case of devices not intended to be transferred to MDR/IVDR. However, there was general agreement that notified bodies should prioritise MDR/IVDR activities and their workload should be adapted accordingly. The Chair informed that a first draft guidance on IVDR Appropriate surveillance is currently under preparation and will be soon shared for consultation.
- **Pre-submission dialogue** between notified bodies and manufacturer: NBO agreed that such an activity is already allowed in respect to "what needs to be fulfilled" but in some cases notified bodies might prefer to be overcautious. It was clarified that exchanges of technical information and regulatory guidance between the notified body and the manufacturer (i.e. on "what needs to be fulfilled") are allowed before (i.e. before application) as well as during the conformity assessment process. On the other hand, it is not allowed for notified bodies to assist manufacturers in finding solutions to fulfil relevant requirements (i.e. on "how to comply").

3. Update MDCG 2019-6

On the update of question III.6 concerning the meaning of the term "employed", COM presented the new proposal prepared following the latest NBO consultation and informed that notified bodies are currently being consulted. A few NBO members informed that they might send further comments shortly.

On application of last indent of MDR/IVDR Annex VII, Section 3.2.3 concerning adequate experience within a notified body, COM informed that the outcome of the consultation was not conclusive. It was agreed to address the matter outside MDCG guidance documents, with a case-by-case approach taking into account the provision on exceptional circumstances provided in Annex VII Section 3.3.1, when appropriate.

4. Status of Team-NB position papers

In the last meeting, members were invited to send their position to questions relating to Team-NB position papers after the meeting. Based on this feedback and on further discussion, NBO agreed that Team-NB position papers are not to be considered as guidance and best practice document according to Annex VII, section 1.6.1 MDR/IVDR. However, work performed by notified bodies should be encouraged at the level of NBCG-Med, also taking into account the proposal that NBCG-Med should make use of a dedicated New Work Item Template and inform MDCG on work intended to be performed. COM informed the members of a possible support by a technical secretariat for the notified body work.

Specific issues related to the Team-NB position papers concerning dental implants and dental abutments will be forwarded back to the B&C WG for follow up.

5. State of play NBO Task Forces and other relevant activities

The group was updated about the state of play of a number of NBO Task Forces (TF):

- TF on designation process: The 1st revision of BPG on designation process sent for NBO endorsement. Work on 2nd revision to start soon.
- TF on list of standard fees: Proposal for a list of standard fees finalised and currently subject to COM internal consultation on potential anti-competitive issues raised by notified bodies. As next step, NBO and NBCG-Med will be consulted.
- TF on appropriate surveillance: First draft regarding IVDR being finalized and to be shared to NBO for consultation soon. Update of MDCG 2022-4 will follow.
- TF on requirements for NB personnel: First meeting took place on 29 April where it was agreed to focus the work on update of NBOG BPG 2017-2 rev.1. NBCG-Med is currently being consulted on application of current guidance. A preference to split the guidance in two separate document for MDR and IVDR was expressed by NBO.
- TF on peer review activities: The TF already met in a number of meeting and the agreed objective is the definition of a mechanism for peer review. A survey of DAs is under finalisation and will be launched among NBO members over the summer period.
- TF on technical documentation assessment report (TDAR): First meeting took place on 28 April TF agreed on a number of key elements / steps, including the need to take into account the work currently performed at IMDRF level. NBCG-Med will be asked to provide “good examples” of templates currently used.

Other work items endorsed by MDCG were presented: Revision of MDCG 2019-13 guidance on sampling and of MDCG 2020-3 on significant changes.

NBO was also informed about relevant on-going international (IMDRF) work items linked to task force on TDAR, as referenced above. In particular on Good Regulatory Review Practices (GRRP) member were invited to send comments on the on-going consultation.

6. Annual report under Article 44 (12) MDR / Article 40 (12) IVDR

COM provided operational indication on how to submit the annual report of DA monitoring and on-site assessment activities, to be uploaded in CIRCA BC in the absence of

EUDAMED. DAs should also provide the summary to be published in a dedicated page of COM Website. It was proposed to use the same CIRCA BC workspace also for the annual assessment plans.

7. AOB

No additional points were brought to the attention of the NBO WG members.

List of participants

NBO members: AT, BE, CY, CZ, DE, DK EE, ES, FI, FR, HU, HR IE, IT, LV, NL, PL, PT, RO, SE, SK.

Observers: NO, TK

COM: SANTE B6, SANTE F5.